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PTO/SB/21 (08-03)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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TRANSMITTAL FORM (to be used for all correspondence after initial filing)	Application Number	10/750,138	
	Filing Date	December 31, 2003	
	First Named Inventor	David Gschneider	
	Art Unit	1616	
	Examiner Name	Not Yet Assigned	
Total Number of Pages in This Submission	8	Attorney Docket Number	01946/100G527-US2

ENCLOSURES (Check all that apply)

<input checked="" type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Response to Missing Parts/ Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____	<input type="checkbox"/> After Allowance Communication to Group <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): IDS Citation by Applicant and two references Certificate of Express Mailing
Remarks		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual name	DARBY & DARBY P.C. Jason C. Chumney, 54,781
Signature	
Date	October 1, 2004



Application No. (if known): 10/750,138

Attorney Docket No.: 01946/100G527-US2

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Transmittal Form (1 page);
Information Disclosure Statement (2 pages);
Fee Transmittal for FY 2004 (1 page);
2 References
List of References (PTO\SB08a\b form) (3 pages); and
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Docket No.: 01946/100G527-US2
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
David Gschneider et al.

Application No.: 10/750,138

Confirmation No.: 9762

Filed: December 31, 2003

Art Unit: 1616

For: COMPOUNDS AND COMPOSITIONS FOR
DELIVERING ACTIVE AGENTS

Examiner: Not Yet Assigned

INFORMATION DISCLOSURE STATEMENT (IDS)

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is filed before the mailing date of a first Office Action on the merits as far as is known to the undersigned (37 CFR 1.97(b)(3)).

Those patent(s) or publication(s) which are marked with a double asterisk (**) next to the Cite No. in the attached form PTO/SB/08 are not supplied because they were previously cited by or submitted to the Office in a prior application number 10/168,275, filed July 15, 2002 and relied upon in this application for an earlier filing date under 35 U.S.C. 120.

A copy of each Foreign patent document on the PTO/SB/08 not previously cited is attached (WO 96/30036 and WO 97/36480).

Copies of U.S. Patent documents that were not previously cited (U.S. 5,401,516 and U.S. 5,443,841) are not required, as this application was filed after June 30, 2003.

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this Information Disclosure statement shall not be construed to be an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

The Commissioner is authorized to charge any deficiency or credit any excess in this fee to Deposit Account No. 04-0100.

Dated: October 1, 2004

Respectfully submitted,

By

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Registration No.: 54,781

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PTO/SB/08a/b (08-03)

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Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	10/750,138
				Filing Date	December 31, 2003
				First Named Inventor	David Gschneider
				Art Unit	N/A
				Examiner Name	Not Yet Assigned
Sheet	1	of	3	Attorney Docket Number	01946/100G527-US2

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	AA**	US-5,776,888-B1	07-07-1998	Leone-Bay et al.	
	AB**	US-5,629,020	05-13-1997	Leone-Bay et al.	
	AC**	US-5,643,957	07-01-1997	Leone-Bay et al.	
	AD**	US-5,766,633	06-16-1998	Milstein et al.	
	AE**	US-5,863,944	01-26-1999	Leone-Bay et al.	
	AF**	US-5,866,536	02-02-1999	Leone-Bay et al.	
	AG**	US-5,650,386	07-22-1997	Leone-Bay et al.	
	AH**	US-3,795,739	03-05-1974	Birkmayer et al.	
	AI**	US-3,939,253	02-17-1976	Bodor et al.	
	AJ**	US-4,061,466	12-06-1977	Sjoholm et al.	
	AK**	US-4,147,767	04-03-1979	Yapel	
	AL**	US-4,207,341	06-10-1980	Hubner et al.	
	AM**	US-4,221,815	09-09-1980	Weyer et al.	
	AN**	US-4,238,506	12-09-1980	Stach, deceased et al.	
	AO**	US-4,239,754	12-16-1980	Sache et al.	
	AP**	US-4,393,192	07-12-1983	Curatolo et al.	
	AQ**	US-4,442,090	04-10-1984	Takeya et al.	
	AR**	US-4,499,299	02-12-1985	Bernstein et al.	
	AS**	US-4,462,991	07-31-1984	Higuchi et al.	
	AT**	US-4,656,161	04-07-1987	Herr et al.	
	AU**	US-4,654,327	03-31-1987	Teng	
	AV**	US-4,692,433	09-08-1987	Hostetler et al.	
	AW**	US-4,757,066	07-12-1988	Shiokari et al.	
	AX**	US-4,835,312	05-30-1989	Itoh et al.	
	AY**	US-4,873,087	10-10-1989	Morishita et al.	
	AZ**	US-4,878,942	11-07-1989	Motegi et al.	
	AA1**	US-4,900,730	02-13-1990	Miyauchi	
	AB1**	US-4,927,928	05-22-1990	Shroot et al.	
	AC1**	US-5,066,487	11-19-1991	Morelle et al.	
	AD1**	US-5,352,461	10-04-1994	Feldstein et al.	
	AE1**	US-5,665,700	09-09-1997	Cho et al.	
	AF1**	US-5,705,529	01-06-1998	Matyus et al.	
	AG1**	US-5,447,728	09-05-1995	Milstein et al.	
	AH1**	US-5,451,410	09-19-1995	Milstein et al.	
	AI1**	US-5,541,155	07-30-1996	Leone-Bay et al.	
	AJ1**	US-5,709,861	01-20-1998	Santiago et al.	
	AK1**	US-5,714,167	02-03-1998	Milstein et al.	
	AL1**	US-5,750,147	05-12-1998	Kantor et al.	
	AM1**	US-Re 35,862	07-28-1998	Steiner et al.	
	AN1**	US-5,792,451	08-11-1998	Sarubbi et al.	
	AO1**	US-5,804,688	09-08-1998	Leone-Bay et al.	

Examiner Signature	Date Considered
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Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/750,138
				Filing Date	December 31, 2003
				First Named Inventor	David Gschneidner
				Art Unit	N/A
				Examiner Name	Not Yet Assigned
Sheet	2	of	3	Attorney Docket Number	01946/100G527-US2

	AP1**	US-5,811,127	09-22-1998	Milstein et al.	
	AQ1**	US-5,876,710	03-02-1999	Leone-Bay et al.	
	AR1**	US-5,879,681	03-09-1999	Leone-Bay et al.	
	AS1**	US-5,939,381	08-17-1999	Leone-Bay et al.	
	AT1**	US-5,958,457	09-28-1999	Santiago et al.	
	AU1**	US-5,965,121	10-12-1999	Leone-Bay et al.	
	AV1**	US-5,989,539	11-23-1999	Leone-Bay et al.	
	AW1**	US-5,990,166	11-23-1999	Leone-Bay et al.	
	AX1**	US-6,001,347	12-14-1999	Leone-Bay et al.	
	AY1**	US-5,773,647	06-30-1998	Leone-Bay et al.	
	AZ1	US-5,401,516	03-28-1995	Milstein et al.	
	AA2	US-5,443,841	08-22-1995	Milstein et al.	
	AB2**	US-4,035,507	07-12-1997	Bodor et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
	BA**	EP0576941	01-05-1994			
	BB**	EP0036145	09-23-1981			
	BC**	EP0365183	04-25-1990			
	BD**	EP0517211	12-09-1992			
	BE**	EP226223	06-24-1987			
	BF**	FR4446	11-02-1966			
	BG**	GB2095994	10-13-1982			
	BH**	JP2239980	09-21-1990			
	BI**	JP4837819	11-14-1973			
	BJ**	ES369853	07-16-1971			
	BK**	WO8807378	10-06-1988			
	BL**	WO9747270	12-18-1997			
	BM	WO9630036	10-03-1996			
	BN	WO9736480	10-09-1997			
	BO**	WO9929705	06-17-1999			

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. *CITE NO.: Those patent(s) or publication(s) which are marked with a double asterisk (**) next to the Cite No. are not supplied because they were previously cited by or submitted to the Office in a prior application relied upon in this application for an earlier filing date under 35 U.S.C. 120. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS

Examiner Initials ²	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
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Examiner Signature		Date Considered	
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known

Application Number	10/750.138
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Filing Date	December 31, 2003
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First Named Inventor	David Gschneidner
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Art Unit	N/A
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Examiner Name	Not Yet Assigned
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Attorney Docket Number 01946/100G527-US2

Sheet 3 of 3

CA**	Picciola G.: "Sintesi Di Acidi Chiazolinioici E Benzossazinonici E Studio Delle Loro Proprieta Antiniammatorie" IT, Societa Chimica Italiana Pavia vol 31, no. 9 pgs 655-664 and English Translation
CB**	Chem Abs 73548-12-6 (4/1991)
CC**	Chem Abs 70204-54-5 (4/1991)
CD**	Chem Abs 184360 -83-342 (1975) "Solubility and disassociation constants of some alicyclic acids
CE**	Chemical Abstract, Vol. 99(23) Abst. No. 191473h (1983)
CF**	Riveria, Theresa M. et al. "Oral Delivery of Heparin in Combination with Sodium N-[8-2-hydroxybenzoyl]amino]caprylate: Pharmacological Considerations" Pharmaceutical Research vol 14(12) 1830-1834 (1997)
CG**	Leone-Bay, A. et al. " The evolution of an oral heparin dosing solution" Drugs of the Future vol 22(8) 885-891 (1997)
CH**	Brayden, D. et al. "Heparin Absorption across the intestine: Effects of Sodium N-[8-2-hydroxybenzoyl]Amino] Caprylate in rat in situ intestinal instillations ind in Caco-2 monolayers" Pharmaceutical Research vol 14(12) 1772-1779 (1997)
CI**	Leone-Bay, A. "Acylated non-alpha-amino acids as novle agents for the oral delivery of heparin sodium, USP" Journal of Controlled Release 50: 41-49 (1998)
CJ**	Leone-Bay, A. "4-[4-(2-Hydroxybenzoyl) amino]phenyl]-butyric Acid as Novel Oral Delivery Agent for Recombinant Human Growth Hormone"; Journal of Medicinal Chemistry vol. 39, no. 13 pp 2571-2578 (1996)
CK**	Leone-Bay, A. "N-Acylated alpha-amino acids as novel oral delivery agents for proteins" "; Journal of Medicinal Chemistry vol 38, 4263-4269 (1995)
CL**	Leone-Bay, A. "N-Acylated alpha-amino acids as novel oral delivery agents for proteins" "; Journal of Medicinal Chemistry vol 38, 4257-4262 (1995)
CM**	Ho Koc-Kan; et al. " A Practical Synthesis of ω -aminoalkanoic acid derivatives form Cycloalkanones" Synthetic Communication, vol. 26, no. 14: 2641-2649 (1996)
CN**	Gurrieri and Siracusa: "Thermal Condensation of Some alpha-aminoacids with Phthalic Acid" Thermochimica Acta, 7 (1973) 231-239
CO**	Amino Yusuke et al. Chem Pharm Bull 36 pgs 4426-4434 (1988)
CP**	Brown et al., J. Med. Chem. 27:79-81 (1984)
CQ**	Johansen, Marianne, et al. "The Kinetics of decompn. Of various N-Mannich bases of salicylamide" Int. J. Pharm. (1980), 7(2): 119-27 (1980)
CR**	Palagiano, F. et al. "Synthesis, stability and anticonvulsant activity of two new GABA prodrugs", » PHARMAZIC, 52(d) : 272-276 (1976), XP-001084051
CS**	Yalcin, I. et al. "Synthesis and Microbiological Activity of Some Novel N-(2-Hydroxyl-5-Substituted phenyl) Benzaacetatemides, Phenyl acetamides and ThiOphenoxyacetamides as the Possible Metabolites of Antimicrobial Active Benzoxazoles," Il Farmaco, 51(11), 685-681 (1977).

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature

Date
Considered